

REMARKS

A. Restriction

In the Restriction Requirement mailed on April 23, 2001, the Examiner restricted pending Claims 59-101 into the following 4 groups:

- Group I: Claims 59-68, drawn to a method of screening modulators providing a biologically active TL-gamma;
- Group II: Claims 69-78, drawn to a method of screening modulators wherein the tail domain shares 60% identity with SEQ ID NO:1;
- Group III: Claims 79-87, drawn to a method of screening modulators wherein the tail domain shares 60% identity with amino acids 602-784 of SEQ ID NO:1; and
- Group IV: Claims 88-101, drawn to a method of screening modulators wherein the tail domain shares 60% identity with amino acids 1-357 of SEQ ID NO:1.

B. Election

Applicants elect, **with traverse**, Group IV, Claims 88-101. Applicants' non-election of the remaining claims does **not** narrow the scope of any of the claims because non-election of these claims is not related to a "statutory requirements for a patent" but rather is related to the Patent Office's convenience for organizing searches. Applicants reserve the right to prosecute the non-elected claims in another application(s).

C. Traversal

Applicants **traverse** the Examiner's restriction of Groups I-IV and request their re-joinder because the Examiner has not established distinctness of Groups I-IV, and because Claim 59 is a linking claim, as further explained below.

1. The Examiner has not established distinctness

The Examiner has not met her burden of establishing that examining Groups I-IV together in a single application creates a serious search burden on the PTO.

It is not enough that the Examiner allege distinctness of the claimed inventions. MPEP 808.02 directs the Examiner that she also "must show by appropriate explanation" one of the following: (a) separate classification of the claimed inventions, (b) a separate status in the art when the inventions are classifiable together, and (c) a different field of search. The Examiner has not provided the requisite explanation for any one of these requirements as further discussed below.

i. The classification is wrong

To insist upon restriction, the Examiner must show separate classification of the claim groups. However, the Examiner misclassified the claims.

Groups I and II were erroneously classified in class 435, subclass 7.4. Class 435, subclass 7.4 refers to "Subject matter in which the measurement or test determines the identity or quantity of an enzyme or group of isoenzymes."¹ However, the claims of Groups I and II do **not** recite identifying TL- γ enzymes, but rather to identifying "modulators"² of TL- γ .

Groups III and IV were mistakenly classified in class 435, subclass 7.6. Class 435, subclass 7.6 refers to "Subject matter involving a modified enzyme which has been functionally changed through recombinant DNA techniques, chemical treatment, etc."³ This classification is **not** applicable because Groups III and IV recite "screening for modulators" rather than "a modified enzyme" *per se*.

In view of the mis-classification of the claims, the first basis for requiring restriction is absent.

¹ Manual of Patent Classification.

² Applicants note that "modulators of TL- γ " nonetheless may encompass an enzyme or group of isoenzymes, but are not restricted to these embodiments.

³ Manual of Patent Classification.

ii. **A separate status in the art is not established**

To insist upon restriction, the Examiner must provide "an explanation [which] indicates a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status."⁴

The Examiner stated that "[e]ach group requires the use of a **different reagent**, wherein the different reagent [*sic.*] are defined as: TL-gamma, TL-gamma with 60% identity to SEQ ID NO:1, a tail domain with 60% identity to amino acids 602-784 and a tail domain with 60% identity to amino acids 1-357. Because each group requires a different reagent, the method of screening associate with the reagent **will cause a different mode of operation**. The different reagents of groups I-IV **will also provide different effects** when comparing the method of screening for modulators because they require the use of different reagents."⁵ It is important to note that the record is devoid of any scientific reasoning or evidence to support either of the Examiner's assertions that the different reagent proteins "will cause a different mode of operation" and "will also provide different effects." The Examiner's conclusory statements are not a substitute for reasoning or evidence.

The Examiner also stated that "the groups are drawn to a plurality of disclosed patentably distinct polypeptides comprising materially different amino acids. The **separate amino acids** bear distinct structural or **biochemical properties**. Therefore, each **amino acid sequence** disclosed is patentably distinct and is considered a separate invention."⁶ However, the Examiner has not explained why, or advanced any evidence to show that, the recited homologs of TL- γ , which have different amino acids, would have the alleged "distinct biochemical properties." Therefore, this requirement has not been satisfied.

iii. **A different field of search has not been shown**

To insist upon restriction, the Examiner must show that "it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists." However, no such showing was provided. Accordingly, this prong is lacking.

⁴ MPEP 808.02 (B).

⁵ (Emphasis added) Paper No. 16, page 2, item 2.

⁶ Emphasis added, Paper No. 16, page 3, first full paragraph.

Since the Examiner has not established any of the three alternative grounds for insisting upon restriction, Applicants respectfully request that restriction of Groups I-IV be withdrawn.

2. **Claim 59 is a linking claim**

The restriction is improper because Claim 59 is a linking claim with respect to Groups I-IV. MPEP 803.03 directs the Examiner that:

"Upon allowance of the linking claim(s), the restriction requirement as to the linked inventions **shall be withdrawn** and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be **entitled to examination in the instant application.**"⁷

MPEP 809.03 defines linking claims to include "genus claims linking species claims." MPEP 806.04(d) further defines a generic claim as follows:

"a generic claim should include no material element additional to those recited in the species claims, and must comprehend within its confines the organization covered in each of the species."

Under the above definition, Claim 59 is a **generic** claim since it does not include additional limitations when compared to any one of Claims 60-101. In particular, the entire recitation of Claim 59 (Group I) is repeated in each of independent Claims 69 (Group II), Claim 79 (Group III), and Claim 88 (Group IV).

Because Claim 59 is a generic linking claim with respect to all of Groups I-IV, MPEP 803.03 requires that the restriction of Groups I-IV "shall be withdrawn."

CONCLUSION

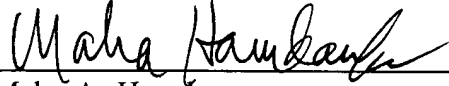
For the reasons set forth above, Applicants respectfully request withdrawal of the restriction of Groups I-IV.

⁷ Emphasis in original.

If a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned.

Dated: October 6, 2003

Signed on behalf of:



Maha A. Hamdan
Registration No. 43,655
101 Howard Street, Suite 350
San Francisco, CA 94105
Tel: 415-904-6500